

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

|                           |   |                            |
|---------------------------|---|----------------------------|
| SHIRE LABORATORIES INC.,  | : |                            |
|                           | : |                            |
| Plaintiff,                | : |                            |
|                           | : | Civil Action No. 05-20 GMS |
| v.                        | : |                            |
|                           | : |                            |
| IMPAX LABORATORIES, INC., | : |                            |
|                           | : |                            |
| Defendant.                | : |                            |

**JOINT REPORT**

Plaintiff Shire Laboratories Inc. ("Shire") and Defendant Impax Laboratories, Inc. ("Impax") submit this Joint Report in preparation for the status and scheduling conference before this Court set for April 11, 2005 at 2:00 pm, pursuant to Rule 16 of the Federal Rules of Civil Procedure and Local Rule 16.2(b).

**1. Jurisdiction and Service.** The parties agree that the Court has subject matter jurisdiction over this action and that the Court has personal jurisdiction over both Shire and Impax. At the present time, Shire and Impax believe that all necessary parties have been served and have appeared.

**2. Substance of the Action.** This is an action for patent infringement that arises out of the statutory and regulatory framework created by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc and 35 U.S.C. §§ 156, 271, 282), commonly known as the Hatch-Waxman Act.

Shire owns U S Patent Nos. 6,322,819 (“the ‘819 Patent”) and 6,605,300 B1 (“the ‘300 Patent”), both entitled “Oral Pulsed Dose Drug Delivery System.” The ‘819 Patent and the ‘300 Patent issued on November 27, 2001 and August 12, 2003, respectively.

Shire also holds New Drug Application (“NDA”) No. 21-303, which was approved by the Food and Drug Administration (“FDA”) for the manufacture and sale of a pharmaceutical composition containing mixed amphetamine salts for the treatment of Attention Deficit Hyperactivity Disorder. Shire markets and sells this composition in the United States under the trade name Adderall XR<sup>®</sup>. Shire listed the ‘819 and ‘300 Patents in the FDA’s “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book,” in connection with NDA No. 21-303 as covering its Adderall XR<sup>®</sup> drug products.

Impax submitted to the FDA an amendment to Abbreviated New Drug Application No. 76-852 (“Impax’s ANDA Amendment”), which it filed under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Impax’s ANDA Amendment seeks approval to engage in the commercial manufacture, use, and sale of generic versions of Shire’s Adderall XR<sup>®</sup> drug products. Specifically, the subject of Impax’s ANDA Amendment are extended-release capsules containing a mixture of four amphetamine salts at the 5 mg, 10 mg, 15 mg, 20 mg and 25 mg strengths (“ANDA Amendment Products”). Because Impax sought approval of its ANDA Amendment Products before the expiration of the ‘819 and ‘300 Patents, Impax’s ANDA Amendment contains a so-called “paragraph IV certification” to these patents. An ANDA applicant with such a paragraph IV certification is required by statute to provide notice of that certification to the NDA holder and the owner of the patents listed in the Orange Book for that NDA. Impax sent Shire a “Notice Under 21 U.S.C. § 355(j)(2)(B)(i) through (iv) With

Reference to U.S. Patent Nos. 6,322,819 and 6,605,300" dated December 1, 2004 ("Notice Letter")

On January 13, 2005 Shire filed a complaint against Impax, alleging that Impax's submission to the FDA of its ANDA Amendment with a paragraph IV certification for the '819 and '300 Patents and for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of its ANDA Amendment Products before the expiration of these patents is an act of infringement of one or more claims of the '819 and '300 Patents under 35 U.S.C. § 271(e)(2)(A), and that such infringement has been willful. Shire also alleges in its complaint that Impax's commercial manufacture, use, sale, offer for sale, or importation into the United States of its ANDA Amendment Products will infringe one or more the claims of the '819 and '300 Patents.

Impax answered Shire's complaint on February 3, 2005. In its answer Impax set forth six affirmative defenses. Impax states that the manufacture, use, or sale of Impax's ANDA Amendment Products has not infringed, does not infringe, and would not, if marketed, infringe any claim of the '819 or '300 Patents (Impax's first and second affirmative defenses). Impax further states that the claims of the '819 and '300 Patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112 (Impax's third and fourth affirmative defenses). Impax also states that the '819 and '300 patents cannot be willfully infringed by the mere act of filing an ANDA or paragraph IV certification of those patents, adding that assertions of willful infringement are not proper in the context of ANDA litigations (Impax's fifth affirmative defense). Impax's sixth affirmative defense alleges that the '819 and '300 Patents are unenforceable.

**3. Identification of Issues.** The issues in dispute are: (1) the infringement of Shire's '819 and '300 Patents by the filing of Impax's ANDA Amendment and the proposed commercial marketing of Impax's ANDA Amendment Products, and (2) the validity of Shire's '819 and '300 Patents, and (3) the enforceability of Shire's '819 and '300 Patents

**4. Narrowing of Issues.**

**4(i) - Shire's Statement Regarding Narrowing of the Issues:** This case is related to *Shire Laboratories Inc. v. Impax Laboratories, Inc.*, Civil Action No. 03-1164 (GMS) ("*Shire v. Impax I*") *Shire v. Impax I* is a patent infringement action that arose out of Impax's submission to the FDA of ANDA No. 76-852. That submission seeks approval for Impax to engage in the commercial manufacture, use and sale of a generic version of Shire's 30 mg Adderall XR® drug product. *Shire v. Impax I* is currently in expert discovery. Fact discovery in *Shire v. Impax I* has already closed and this Court has issued a Markman ruling.

The instant action ("*Shire v. Impax II*") involves five different drug products that are different from the single product of *Shire v. Impax I*. The parties agree that discovery activities completed in *Shire v. Impax I* shall be applied in *Shire v. Impax II*. Specifically, the parties shall stipulate that all written discovery and depositions in *Shire v. Impax I* shall be treated as if produced, exchanged or taken in *Shire v. Impax II*. The parties shall further stipulate that the Protective Order entered in *Shire v. Impax I* shall apply in *Shire v. Impax II*.

Presently there are no dispositive or partially dispositive issues appropriate for decision on motion.

**4(ii) - Impax's Statement Regarding Narrowing of the Issues:** This case deals with nearly identical issues to *Shire Laboratories Inc. v. Impax Laboratories, Inc.*, Civil Action No. 03-1164 (GMS) ("*Shire v. Impax I*") *Shire v. Impax I* is a patent infringement action that

arose out of Impax's submission to the FDA of ANDA No. 76-852. That submission seeks approval for Impax to engage in the commercial manufacture, use and sale of a generic version of Shire's 30 mg Adderall XR® drug product. *Shire v. Impax I* is currently in expert discovery. Fact discovery in *Shire v. Impax I* has already closed and this Court has issued a Markman ruling on the claims of the patents-in-suit.

Given that the instant action ("*Shire v. Impax II*") is related to *Shire v. Impax I*, the parties agree that discovery activities completed in *Shire v. Impax I* shall be applied in *Shire v. Impax II*. Specifically, the parties shall stipulate that all written discovery and depositions in *Shire v. Impax I* shall be treated as if produced, exchanged or taken in *Shire v. Impax II*. The parties shall further stipulate that the Protective Order entered in *Shire v. Impax I* shall apply in *Shire v. Impax II*.

*Shire v. Impax II* involves the same proposed generic product as is the subject of the *Shire v. Impax I* action, but in different dosages. The issues presented in *Shire v. Impax II* in relation to infringement, invalidity and unenforceability are identical in almost every respect.<sup>1</sup>

The date for filing letter briefs in *Shire v. Impax I*, to enable the parties to file dispositive motions is presently scheduled for April 8, 2005. Impax expects to file at least one such letter brief and expects the ruling on this to be dispositive of the issues presented in *Shire v. Impax II*.

**5. Relief.** Shire currently seeks a judgment declaring that the effective date of any approval of Impax's ANDA Amendment Products be no earlier than the date on which the last of the '819 and '300 Patents expires. Shire also seeks a judgment preliminarily and permanently enjoining Impax from engaging in the commercial manufacture, use, offer to sell or sale within

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<sup>1</sup> Currently pending before the Court is the issue of whether Impax can amend the pleadings to assert the affirmative defense of inequitable conduct. If the Court were to grant this motion, all issues would be identical in both *Shire v. Impax I* and *Shire v. Impax II*, except for the dosage strength.

the United States or importation into the United States of Impax's ANDA Amendment Products until the expiration of the last of the '819 and '300 Patents. Shire requests that the Court award Shire costs, expenses and attorneys' fees in this action, which amounts are not presently known.

Impax seeks a dismissal of Shire's Complaint, with prejudice, based upon its affirmative defenses of non-infringement, invalidity, and unenforceability as well as costs

6. **Amendment of Pleadings.** The parties propose that amendment of pleadings without leave of Court must occur by July 29, 2005.

7. **Joinder of Parties.** The parties propose that joinder of all parties must occur by July 29, 2005.

8. **Discovery.** The parties propose the following discovery schedules:

#### **Discovery Proposals**

The parties differ as to a joint proposed schedule. Therefore, each of the parties has submitted their own proposed schedules.

#### **8(i) – Shire's Proposed Schedule**

| Event  | Date              |
|--|-------------------|
| <b>Fact Discovery</b>  |                   |
| Exchange of Initial Disclosures  | April 15, 2005    |
| Filing of Amended Pleadings<br>w/o Leave of Court                        | July 29, 2005     |
| Completion of Joinder of<br>Additional Parties                           | July 29, 2005     |
| Reliance of Advice of Counsel<br>As A<br>Defense to Willful Infringement | October 3, 2005   |
| Production of Opinions On<br>Which Defendant Intends to<br>Rely          | October 10, 2005  |
| Completion of Fact Discovery   | November 14, 2005 |

| <b>Event</b>                                    | <b>Date</b>                                 |
|---|---|
| <b>Markman Proceedings</b>                      |   |
| Submission of Joint Claim Construction Chart    | 7 weeks prior to Markman Hearing            |
| Exchange of Opening Claim Construction Briefs   | 6 weeks prior to Markman Hearing            |
| Exchange of Answering Claim Construction Briefs | 4 weeks prior to Markman Hearing            |
| Markman Hearing                                 | January 2006                                |
| <b>Expert Discovery</b>                         |   |
| Opening Expert Reports (burden of proof)        | February 10, 2006                           |
| Answering Expert Reports                        | February 24, 2006                           |
| Completion of Expert Discovery                  | March 10, 2006                              |
| <b>Dispositive Motions</b>                      |   |
| Opening Letter Briefs                           | March 17, 2006                              |
| Answering Letter Briefs                         | March 31, 2006                              |
| Reply Letter Briefs                             | April 7, 2006                               |
| Opening Summary Judgment Motion Brief           | 14 Days After Court Decides Letter Briefing |
| <b>Trial Phase</b>                              |   |
| Pretrial conference                             | September, 2006                             |
| Trial   | October, 2006                               |



### **8(ii) - Impax's Proposed Schedule**

Impax proposes that, due to the significant overlap of the issues presented in *Shire v. Impax II* of the issues presented in *Shire v. Impax I*, the Court should stay discovery in *Shire v. Impax II* until completion of *Shire v. Impax I*. *Shire v. Impax II* involves the identical proposed generic product as in *Shire v. Impax II*, the only difference between *Shire v. Impax I* and *Shire v. Impax II* is the strength of the proposed dosages. *Shire v. Impax II* relates to the 5, 10, 15, 20 and 25 mg generic version of Adderall XR®, while *Shire v. Impax I* relates to the 30 mg generic version of Adderall XR®. All other issues of infringement, invalidity and possibly unenforceability<sup>2</sup> are identical. Further, as *Shire v. Impax I* will be dispositive of the issues presented in *Shire v. Impax II*, it would be a waste of judicial resources to duplicate the discovery. If *Shire v. Impax II* were to proceed there would be a waste of judicial resources, a disruption to the Parties and any relevant third party regarding discovery, and a waste of time and resources.

Further, Impax proposes that as the issues are nearly identical in *Shire v. Impax II* as *Shire v. Impax I*, it is unclear what additional discovery would be necessary. Due to the significant overlap in the litigations, Impax proposes that there be minimal discovery focused on the issues, if any, that do not overlap between the two litigations.

### **Parties Proposed Discovery Limits**

The parties differ as to discovery limits. Therefore, each of the parties has submitted their own proposed discovery limits.

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<sup>2</sup> Currently pending before the Court is the issue of whether Impax can amend the pleadings to assert the affirmative defense of inequitable conduct. If the Court were to grant this motion, all issues would be identical in *Shire v. Impax I* and *Shire v. Impax II*, except for the dosage strength.



**Shire's Proposed Discovery Limits**

Shire proposes that at this time the parties adhere to the limitations on discovery set forth in the Federal Rules of Civil Procedure, except as set forth below, including:

- (a) Limiting the number of depositions to eighteen (18) pursuant to Rule 30(a)(2)(A), other than expert depositions, and the parties shall consult and negotiate in good faith to agree on depositions conducted under Rule 30(b)(6);
- (b) Limiting the length of a deposition to one day of seven (7) hours pursuant to Rule 30(d)(2); and
- (c) Limiting the number of interrogatories in accordance with Del. Local Rule 26 1(b) to 50 interrogatories.

**Impax's Proposed Discovery Limits**

Impax proposes that at this time the parties adhere to the limitations on discovery set forth in the Federal Rules of Civil Procedure, except as set forth below, including:

- (a) Impax proposes that there be no further depositions in *Shire v. Impax II* as the issues overlap with *Shire v. Impax I* and Shire was allowed discovery regarding the lower dosage strengths, and therefore it is unclear that any additional discovery is necessary;
- (b) Impax states that this section should be deleted as it is unnecessary for any further discovery; and
- (c) Impax proposes that no further interrogatories are necessary as the issues in *Shire v. Impax II* overlap with *Shire v. Impax I*.

**9. Estimated Trial Length.** The parties estimate 1 week for this action to be tried

At the present time Shire does not have any issues that it believes should be bifurcated for trial.


**10. Jury Trial.** Neither party has filed a demand for a jury trial in this action.

**11. Settlement.** During the Rule 26(f) teleconference counsel for the parties raised the issue of settlement and determined that settlement discussions would not be productive at this time. Counsel agreed that the first point at which settlement discussions may be constructive would be at the close of fact discovery. The parties note that a teleconference is scheduled for April 6, 2005 at 10:00 am with Magistrate Judge Thyng in *Shire v. Impax I* to discuss alternative dispute resolution, including a mediation conference.

**12. Other Matters.** The parties do not have any other issues they wish to confer about or raise before the Court at this time.

**13. Confirmation of Rule 26(f) Teleconference.** Counsel for Shire and Impax have conferred regarding each of the 12 topics listed above.

Should the Court have any questions regarding the information set forth above, counsel for both parties are prepared to provide the additional information needed to address the Court's concerns.

  
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UNITED STATES DISTRICT COURT  
DISTRICT OF DELAWARE

**CERTIFICATE OF SERVICE**

I hereby certify that on April 4, 2005, I electronically filed the foregoing with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following and which has also been served as noted:

**BY HAND**

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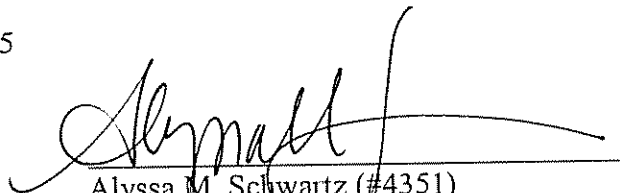
I hereby certify that on April 4, 2005, the foregoing document was sent to the following non-registered participants in the manner indicated:

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